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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,157	07/12/2002	Takashi Saito	NAII 118755	9352

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EXAMINER

SCHNIZER, RICHARD A

ART UNIT PAPER NUMBER

1635

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

10/070,157

Applicant(s)

SAITO, TAKASHI

Examiner

Richard Schnizer, Ph. D

Art Unit

1635

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 22 May 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☒ The Notice of Appeal was filed on 22 May 2006. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: 40-43, 52-55, 64, 65, 67, 68, 73, 78 and 83.  
Claim(s) rejected: 32, 34, 37-39, 44, 46, 49-51, 56, 58, 60-63, 66, 69, 74 and 79.  
Claim(s) withdrawn from consideration: 84-90 and 93-97.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

Continuation of 5. Applicant's reply has overcome the following rejection(s): Indefiniteness rejections of all claims, enablement rejection of claims 73, 78, and 83.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments regarding the obviousness rejection are unpersuasive. Applicant argues at page 16 of the response that Berg fails to teach a method of perforating a cell membrane. This is incorrect. The method of Berg includes illumination of photosensitizers that generate reactive oxygen species that subsequently damage membranes. When this process occurs, for example, in a lysosome, the contents of the lysosome are released, indicating perforation of the lysosome membrane. Applicant argues that Berg fails to disclose that the membrane recovers to the state prior to perforation. This is unpersuasive. Berg taught the use of photosensitizers and illumination to release molecules from various membrane bound organelles of a cell (such as golgi and lysosomes) while retaining functionality of the cell. It would therefore be obvious to optimize the amount of photosensitizer and light exposure used such that cellular damage is minimized, i.e. such that organellar membrane damage is sufficient to allow release of molecules, but not so great as to damage the cell's function. Repair of membrane damage is a process that is performed naturally in cells, such that one of ordinary skill in the art would reasonably expect a cell to repair membranes damaged by the method of Berg, resulting in recovery to the state prior to perforation. Regarding the Chen reference, Applicant argues in the paragraph bridging pages 16 and 17 that Chen is concerned with tissue level therapy, not perforating membranes. This is unpersuasive. Tissue is composed of cells, and the apparatus of Chen allows the delivery to cell membranes of photosensitizers that result in perforation of those membranes. For this reason Applicant's arguments on page 17 regarding "infusing the photoreactive agent into the treatment site" are unpersuasive. As applicant points out, such an infusion results in absorption of the agent into cells. This is followed by illumination of the cells and membrane perforation. Applicant argues that there is no motivation to combine Berg and Chen because Berg is concerned with cells and Chen is concerned with tissues. This is unpersuasive because tissues are composed of cells, and the method of Chen, like the method of Berg requires the delivery of photosensitizing agents to cells. The method would not function otherwise. For these reasons the rejection is maintained.



RICHARD SCHNIZER, PH.D.  
PRIMARY EXAMINER